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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,454	06/11/2001	Mervyn J. Monteiro	4115-161	2105

7590

09/25/2002

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/25/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/878,454

Applicant(s)

FORCHHEIMER ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

It is noted that the claims of the instant application have been determined to include linking claim 1. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct inventions linked by claims 1 and 10:

Groups 1-14. Claims 1-3, 5-11, 23, drawn to a method for reducing induced apoptosis, comprising inhibiting the interaction of presenillin 2 of SEQ ID NO:2 with a homology of SEQ ID NO:2, wherein inhibiting said interaction is facilitated by substitution of amino acid residue 287, 288 or 297 or a combination of substitution of amino acid residues 287, 288 and 297 of SEQ ID NO:1, and/or

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substitution of at least one amino acid residue in the calcium-binding EF-hands of SEQ ID NO:2, or at least one N-terminal residue at position 1 to 3 of SEQ ID NO:2. A method using a single mutation of SEQ ID NO:1, or four possibility, or a single mutation of SEQ ID NO2, , or two possibility, or a combination of one of said four mutations of SEQ ID NO:1 and one of said two mutations of SEQ ID NO:2, or 8 possibility, constitutes a single invention, classified in class 514, subclass 2.

Groups 15-28. Claims 1-3, 4, 5-11, drawn to a method for reducing induced apoptosis, comprising inhibiting the interaction of presenillin 2 of SEQ ID NO:2 with a homology of SEQ ID NO:2, wherein SEQ ID NO:2 also has reduced interaction with presenilin 1 or SEQ ID NO:3, and wherein inhibiting said interaction is facilitated by substitution of amino acid residue 287, 288 or 297 or a combination of substitution of amino acid residues 287, 288 and 297 of SEQ ID NO:1, and/or substitution of at least one amino acid residue in the calcium-binding EF-hands of SEQ ID NO:2, or at least one N-terminal residue at position 1 to 3 of SEQ ID NO:2. A method using a single mutation of SEQ ID NO:1, or four possibility, or a single mutation of SEQ ID NO2, , or two possibility, or a combination of one of said four mutations of SEQ ID NO:1 and one of said two mutations of SEQ ID NO:2, or 8 possibility, constitutes a single invention, classified in class 514, subclass 2.

Group 29. Claim 12, drawn to a mutant of SEQ ID NO:2 at at least one amino acid residue in at least one calcium binding EF-hands of SEQ ID NO:2, classified in class 530, subclass 350.

Groups 30-33. Claims 13-16, drawn to a nucleic acid molecule encoding a mutant of SEQ ID NO:2, at position 2, 127 or 172, or at a combination of positions 2, 127 and 172, a vector comprising said nucleic acid, and a host cell transformed with said vector. Each nucleic acid encoding a single mutation type at position 2, 127 or 172, or at a combination of positions 2, 127 and 172, or four possibility, constitutes a single invention, classified in class 536, subclass 23.1.

Group 34. Claim 17, drawn to a mutant of SEQ ID NO:2 at at least one amino acid penultimate N-terminal residue, classified in class 530, subclass 350.

Groups 35-38. Claims 18-22, drawn to a mutant of SEQ ID NO:1 at position 287, 288 or 297, or at a combination of positions 287, 288 and 297. Each mutant at a single amino acid position 287, 288 or 297, or at a combination of positions 287, 288 and 297, or four possibility, constitutes a single invention, classified in class 530, subclass 350.

In addition, upon the election of any of groups 1-28, further election of the following patentably distinct species of the claimed invention is required:

Mutation at one amino acid residue or a combination of amino acid residues at positions 116-128 and positions 161-173 of the calcium-binding EF hands of SEQ ID NO:2.

Mutations at one N-terminal amino acid residue or a combination of N-terminal amino acid residues 1-3 of SEQ ID NO:2.

Upon the election of group 29, further election of the following patentably distinct species of the claimed invention is required:

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Mutation at one amino acid residue or a combination of amino acid residues at positions 116-128 and positions 161-173 of the calcium-binding EF hands of SEQ ID NO:2.

Upon the election of group 34, further election of the following patentably distinct species of the claimed invention is required:

Position 2 or 3 of SEQ ID NO:2.

The inventions are distinct, each from the other because of the following reasons:

Inventions (1-28) and (29-38) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein.

The methods of groups 1-28 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The products of groups 29-38 as disclosed are structurally distinct.

The species are distinct because they are structurally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

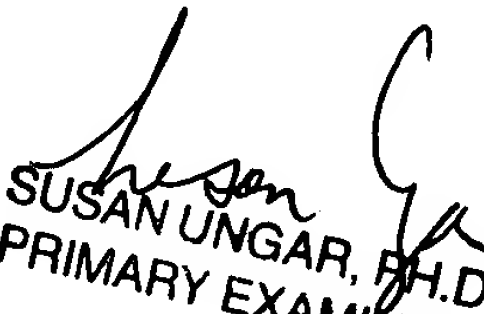
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

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MINH TAM DAVIS

September 23, 2002